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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 08/897,455 | 07/22/97 | STACHE | U 2481.1403-02 |

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| | |
|-----------------------|--------------|
| EXAMINER | |
| BADIO, B | |
| ART UNIT | PAPER NUMBER |
| 1616 | 22 |
| DATE MAILED: 11/05/98 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/897,455

Applicant(s)
Stache et al.

Examiner
Barbara Badio

Group Art Unit
1616



☒ Responsive to communication(s) filed on Sep 15, 1998

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1, 3-5, 7, and 8 is/are pending in the application.

Of the above, claim(s) 3 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 4, 5, 7, and 8 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Final Office Action on the Merits

Status of the Application

1. The amendment filed September 15, 1998 has been entered. Claims 1, 3-5 and 7-8 are pending in the present application. Claim 3 stands withdrawn from further consideration as being drawn to a non-elected invention. Claims 1, 4-5 and 7-8 stand rejected as indicated below.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

3. The rejection of claim 7, under 35 USC 112, second paragraph, as being incomplete is maintained.

Claim 7 as amended lacks a definition of R(2). Does applicant intend R(2) to be as defined in claim 1 or is R(2) as was defined in original claim 7? It is noted that the claim 7 does not end with a period.

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Claim Rejections - 35 USC § 103

4. The rejection of claims 1, 4-5 and 7 under 35 USC 103(a) over Page et al. ('971) is maintained and claim 7 is rejected under 35 USC 103(a) over Page et al. ('971).

3 Applicant argues (1) there is no teaching or suggestion in the reference to modify the exemplified prior art compounds to obtain the claimed compound(s); (2) that the decisions cited by the examiner do not deal with claims directed to compounds such as presently claimed; and (3) the genus of the reference is very large considering the number of variables taught. The argument is not persuasive for the following reasons:

The claimed invention is drawn to a genus of corticoid esters wherein the ester substituent attached to the 21-position contains an aralkyl group. There are a number of variables at the 6-, 9-, 11-, 16- and 17-positions as well as an optional 9(11)- double bond. Thus, unlike In re Baird the present invention encompasses numerous compounds based on the various combination of variables defined by the instant claims. *In re Baird* is not an appropriate decision in the present case based on the number of compounds encompassed by the claimed invention. In Baird, the applicant was claiming a single compound which was encompassed by the broad genus of the cited prior art reference. However, the court decided there was no motivation to select the single claimed compound from among many taught by the reference. However, in

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the present case, both the claimed invention and the prior art encompass numerous compounds. Thus, the decisions cited by the examiner are more appropriate than that of *In re Baird* in the present situation.

The examiner notes applicant's argument that the cases cited by the examiner do not deal with the instantly claimed compounds. The examiner did not intend to imply ~~said~~ that the cited decisions dealt with similar compounds. However, both of the cited cases dealt with the issue of limiting a reference to the exemplified subject matter. In both decisions, it was held that a reference should be evaluated based on what it teaches the ordinary artisan and not limited to the exemplified subject matter. Again, the examiner notes that examples 9 and 19 of the cited reference differ only in the exemplified group at the 21-position. However, the reference teaches an equivalence between hydroxyl and an acyloxy group (i.e., acyloxy groups having either an alkyl or an aralkyl moiety) at the 21-position. The motivation to make the claimed compound(s) is based on the teaching of equivalency by the prior art.

For these reasons and those given in Paper Nos. 14 and 20, the rejection of claims 1, 4-5 and 7 under 35 USC 103(a) over Page et al. ('971) is maintained and claim 7 is rejected under 35 USC 103(a) over Page et al. ('971).

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Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Telephone Inquiry Contacts

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara Badio whose telephone number is (703) 308-4595. The examiner can normally be reached between 7:30 am and 4 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, José Dees, can be reached on (703) 308-4628. The fax phone number for this Group is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.


JOSE G. DEES
SUPERVISORY PATENT EXAMINER
1616

BB
October 30, 1998